Remarks

Applicant has cancelled claims 1 and 13 and added new claims 46 through 49 to overcome the rejection of those claims by the Examiner under 35 U.S.C. 102(e) and 35 U.S.C. §103(a) under Wiesel and Wiesel in view of Jacobs, respectively . The Examiner cites Wiesel as teaching a unit package for carrying and applying a dental composite, wherein the composite 16 is carried on a carrier film 12 with an enlarged central portion 14 that is covered by a film covering 18. Applicant would distinguish the tooth whitening substance carried in Wiesel as other than a curable dental restorative composite as well as the structural aspects of the carrying components. Wiesel discloses a tooth whitening delivery system. The whitening agent includes a gel carried in a channel formed in the central area of a strip of core material. The core is biodegradable. The materials and procedures using the materials in Wiesel bear little relation to Applicant's invention, other than they are applicable to the teeth. A definition of "dental composite" as appearing in Wikipedia, the free encyclopedia appearing on the Internet, is enclosed.

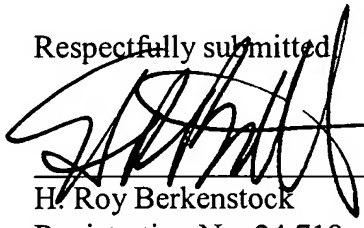
Applicant's invention, as presently distinctly claimed requires substructure differing than that disclosed in Wiesel, and is applied to the tooth totally differently than Wiesel. Applicants carrier is a high tensile strength polyester film upon which is placed a unit dose of a restorative material which must be shaped on a tooth by a dentist using a spatula. As is evident from the new claims, the physical configuration of the carrier film is of a novel shape and distinctive from the rectangular shape of Wiesel. The shape is necessitated by the spatuling procedure for which the Wiesel pad is unusable. The Wiesel whitening system is laid front to back over the crown of the tooth, whereas Applicant's system is disposed around the tooth with the embrasure dams adjacent the sides of the tooth to contain the composite being worked by spatula.

The remaining references cited by the Examiner are generally non-relevant, in that they are directed to packaging techniques no longer subject of the main claims. None of the references cited by the Examiner (alone, or in combination) address a unit package disposed on a high tensile strength film for the application of a composite on the surface of a tooth, adapted for the manipulation (spatuling) of the composite wherein the composite is under the film and the spatuling is performed on the outer face thereof, and the structural requirements of the film. "A claim is

anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Wiesel does not disclose the elements of Applicants restoration kit as now claimed. In respect of the rejection of Applicant's claims on the ground of obviousness, it is important to consider the rules for combining references: a *prima facie* case of obviousness requires three criteria to be met - some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the are, secondly, there must be some reasonable expectation of success and thirdly, the prior art references must teach or suggest all the claim limitations. See *Teleflex, Inc. v. Fiacosa North America Corp.*. 63 USPQ2d 1374, 1387 (Fed. Cir. 20020; *In re Dembiczak*, 50 USPQ2d 1614. 1618 (Fed. Cir. 1999). As now claimed, none of the combinations of references applied by the Examiner meet the prima facie test, or, for that matter the combinability tests of *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303, 11 (Fed. Cir. 1983) and *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 USPQ 929, 933 (Fed. Coir. 1984). The reference Wiesel is directed to application of a tooth whitener substance wherein tabs are applied over the patient's gum, and then removed and the whitener gel is then washed away. Davis and Jacobs are directed to a blister sheet package for such as pills and curable materials, wherein there is no suggestion as to the combinability with special purpose packaging for the application of a restorative dental composite to the surface of a tooth.

Applicant submits that the claims are now in allowable format and an Allowance is solicited. If the Examiner feels that a telephone conference with Applicant's attorney would advance the prosecution of the application, he is invited to call the undersigned at 901-537-1108.

Respectfully submitted,



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CERTIFICATE UNDER 37 CFR 1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Mail Stop RCE, P.O. Box 1450, Alexandria, Virginia, 22313-1450 on February 28, 2007.

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Date: February 28, 2007

Dental composite

From Wikipedia, the free encyclopedia

Dental composites are a group of restorative materials used in dentistry. As with other composite materials, a dental composite typically consists of a resin-based matrix, such as a methacrylate resin like urethane dimethacrylate (UDMA), and an inorganic filler such as silicon dioxide silica. Compositions vary widely, with proprietary mixes of resins forming the matrix, as well as engineered filler glasses and glass-ceramics. The filler gives the composite wear resistance and translucency. A coupling agent such as silane is used to enhance the bond between these two components. An initiator package begins the polymerization reaction of the resins when external energy (light/heat etc.) is applied. A catalyst package can control its speed.

Direct Dental Composites

Direct dental composites can be used for:

- Filling cavities in teeth, as fillings, inlays and/or onlays
- Filling gaps (diastemas) between teeth using a shell-like veneer or
- Minor reshaping of teeth
- Partial crowns on single teeth

Direct dental composites are placed by the dentist in a clinic setting. Polymerization is accomplished typically with a handheld curing light that emits specific wavelengths keyed to the initiator and catalyst packages involved.

The main advantage of a direct dental composite over traditional materials such as amalgam is improved aesthetics. Composites can be made in a wide range of tooth colours allowing near invisible restoration of teeth. Composites are glued into teeth and this strengthens the tooth's structure. The discovery of acid etching of teeth to allow a micromechanical bond to the tooth allows good adhesion of the restoration to the tooth. This means that unlike silver filling there is no need for the dentist to create retentive features destroying healthy tooth. The acid-etch adhesion prevents microleakage, however, all white fillings will eventually leak slightly. Very high bond-strengths to tooth structure, both enamel and dentine can be achieved with the current generation of dentine bonding agents. The downside to composite when compared to amalgam are a shorter lifespan of the filling, and the high likelyhood of requiring root canal therapy if the failure of the filling is not caught quickly. Amalgam fillings may crack a portion of the tooth off, but otherwise tend to fail at a much slower rate.

Initially, composite restorations in dentistry were very prone to leakage and breakage due to weak compressive strength. In the 1990s and 2000s composites were greatly improved and are said to have a compression strength adequate enough for them to be placed in back teeth. The placement of composite requires meticulous attention to procedure or it may fail prematurely. The tooth must be kept perfectly dry during placement or it will likely fail to adhere to the tooth. Composites are placed while still in a soft, dough-like state, but when exposed to light of a certain blue wavelength, they polymerize and harden into the solid filling. It is challenging to harden all of the composite, since the light often does not penetrate more than 2-3 mm into the composite. If too thick an amount of composite is placed in the tooth, the composite will remain partially soft, and this soft unpolymerized composite could ultimately irritate or kill the tooth's nerve. A good dentist will place a deep filling in numerous increments, curing each 2-3mm section fully before adding the next. In addition, the clinician must be careful to adjust the bite of the composite filling, which can be tricky to do. If the filling is too high, even by a subtle amount, that could lead to chewing sensitivity on the tooth. A properly placed composite is comfortable, aesthetically pleasing, strong and durable, and could last 10

years or more. (By most North American insurance companies 2 years minimum)

Indirect Dental Composites

Indirect dental composites can be used for:

- Filling cavities in teeth, as fillings, inlays and/or onlays
- Filling gaps (diastemas) between teeth using a shell-like veneer or
- Reshaping of teeth
- Full or Partial crowns on single teeth
- And even bridges spanning 2-3 teeth

This type of composite is cured outside the mouth, in a processing unit that is capable of delivering higher intensities and levels of energy than handheld lights can. Indirect composites can have higher filler levels, and are cured for longer times. As a result, they have higher levels and depths of cure than direct composites. For example, an entire crown can be cured in a single process cycle in an extra-oral curing unit, compared to a millimeter layer of a filling.

As a result, full crowns and even bridges (replacing multiple teeth) can be fabricated with these systems. A stronger, tougher and more durable product is likely.